

IN THE CLAIMS:

Please cancel claims 31 and 40 without prejudice.

Please amend claims 1 and 7, 34, 41, 47 to read as follows.

1. (Currently amended) A method of inhibiting cell proliferation in a tumor of a patient by orally administering a gastric retention solid dosage form or liquid composition containing irinotecan to the patient,

wherein the dosage form or liquid composition is retained in the stomach for a period of three hours or more and releases the irinotecan in the patient's stomach and at least a portion of the released irinotecan is converted into a metabolite before it is absorbed into the patient's bloodstream,

wherein the metabolite can exist in an active lactone form and an inactive hydroxy acid form,

wherein, the bioavailability of the lactone form of the metabolite is greater than the bioavailability of the lactone form of the metabolite when irinotecan is administered in a non-gastric retention solid dosage form or liquid composition, resulting in enhanced systemic delivery of the active form of the metabolite to the tumor.

2. (Original) The method of claim 1 wherein bioavailability is measured by the area under a curve of bloodstream concentration of the metabolite versus time.
3. (Original) The method of claim 2 wherein the relative bioavailability of the lactone form of the metabolite versus intravenous bioavailability, taken as the area under the

bloodstream concentration curve for gastric retention administration divided by the area under the bloodstream concentration curve for intravenous administration, is about 0.5 or higher.

4.-6. (Canceled)

7. (Currently amended and previously amended) A solid pharmaceutical dosage form for enhanced systemic delivery of irinotecan comprising irinotecan and a gastric retention vehicle composition comprising a hydrogel, wherein the dosage form expands upon contact with gastric fluid and wherein after ingestion by a patient the gastric retention vehicle composition expands to retain the dosage form in the patient's stomach for a prolonged period of timethree hours or more.

8.-9. (Canceled)

10. (Previously amended) A method of inhibiting cell proliferation in a tumor of a patient afflicted with meta-static carcinoma of the colon or rectum by orally administering a dosage form of claim 7 to the patient.
11. (Previously amended) A method of inhibiting cell proliferation in a tumor of a patient afflicted with meta-static carcinoma of the colon or rectum by executing a therapeutic program of repeated oral administration of dosage forms of claim 7 to the patient.

12. (Original) The method of claim 11 wherein the dosage forms contain a unit dose of from about 20 to about 250 milligrams of irinotecan.
- 13.-31. (Canceled).
32. (Original) The solid pharmaceutical dosage form of claim 7 wherein the gastric retention vehicle composition further comprises tannic acid.
33. (Original) The solid pharmaceutical dosage form of claim 7 wherein the gastric retention vehicle composition further comprises a superdisintegrant.
34. (Currently amended) The solid pharmaceutical dosage form of claim 33 wherein the superdisintegrant is selected from the group consisting of ~~crossovidone~~crospovidone, croscarmellose sodium, sodium starch glycolate and mixtures thereof.
35. (Original) The solid pharmaceutical dosage form of claim 33 wherein the hydrogel is selected from the group consisting of hydroxypropyl methylcellulose and mixtures of hydroxypropyl methylcellulose and hydroxypropylcellulose.
36. (Original) The solid pharmaceutical dosage form of claim 35 wherein the gastric retention vehicle composition comprises:
- a) from about 20 to about 70 weight percent of the hydrogel, the hydrogel comprising hydroxypropyl methylcellulose and hydroxypropylcellulose in a weight ratio of from about 1:3 to about 5:3;

- b) from about 25 to about 75 weight percent of the superdisintegrant, and
 - c) from about 2 to about 10 weight percent tannic acid.
37. (Original) The solid pharmaceutical dosage form of claim 36 wherein the gastric retention vehicle composition comprises:
- a) from about 30 to about 55 weight percent superdisintegrant,
 - b) about 5±2 weight percent tannic acid, and
 - c) an amount of hydrogel sufficient to bring the total weight percent to 100.
38. (Original) The solid pharmaceutical dosage form of claim 36 wherein the gastric retention vehicle composition comprises:
- a) from about 10 to about 20 weight percent hydroxypropyl methylcellulose,
 - b) from about 45 to about 50 weight percent hydroxypropyl cellulose,
 - c) from about 25 to about 35 weight percent sodium starch glycolate, and
 - d) from about 4 to about 10 weight percent tannic acid.
39. (Original) The solid pharmaceutical dosage form of claim 36 wherein the gastric retention vehicle composition comprises:
- a) from about 10 to about 30 weight percent hydroxypropyl methylcellulose,
 - b) from about 40 to about 60 weight percent hydroxypropyl cellulose,
 - c) from about 7 to about 35 weight percent croscarmellose sodium, and
 - d) from about 4 to about 10 weight percent tannic acid.
40. (Canceled)

41. (Currently Amended) The solid pharmaceutical dosage form of claim 407 wherein the prolonged period of timed dosage form is retained in the patient's stomach for about five hours or more.
42. (Original) The solid pharmaceutical dosage form of claim 7 wherein the gastric retention vehicle composition expands in volume at least about three fold.
43. (Original) The solid pharmaceutical dosage form of claim 42 wherein the gastric retention vehicle composition expands in volume at least about five fold.
44. (Original) The solid pharmaceutical dosage form of claim 43 wherein the gastric retention vehicle composition expands in volume at least eight about fold.
45. (Original) The solid pharmaceutical dosage form of claim 7 wherein the gastric retention vehicle composition expands to its fullest extent within about fifteen minutes.
46. (Original) The solid pharmaceutical dosage form of claim 45 wherein the gastric retention vehicle composition expands to its fullest extent within about five minutes.
47. (Currently amended) The solid pharmaceutical dosage form of claim 7 in the form of a capsule comprising an acid degradable shell and the antineoplastic agent irinotecan and gastric retention vehicle composition as filling.

48. (Original) The solid pharmaceutical dosage form of claim 7 wherein the dosage form is ovoid or elliptical in shape.
49. (Original) The solid pharmaceutical dosage form of claim 48 having dimensions of from about 4 mm to about 8 mm in two dimensions and from about 10 mm to about 20 mm in the third dimension.
50. (Original) The solid pharmaceutical dosage form of claim 49 having dimensions of about 6 mm by about 6 mm by about 16 mm.